K013663
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CONFIDENTIAL

DEC 0 5 2001

CEMENT RESTRICTOR (CR)
510(k) Summary
November 2001

I. **Company:** Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proposed Proprietary Trade Name:**

CEMENT RESTRICTOR (CR)

III. **Device Description:**

The subject CEMENT RESTRICTOR is a tapered block that is made from POLYETHERETHERKETONE (PEEK). The device is intended to be used in conjunction with standard PMMA cement.

Implants are manufactured out of medical-grade titanium alloy such as described by ASTM F136 or ISO 5832-3. The CEMENT RESTRICTOR implants may also be manufactured from 70:30 Polylactic Acid (Poly (L-lactide-co-D, L -lactide) 70:30, amorphous). Alternatively, the entire system may be made out of POLYETHERETHERKETONE (PEEK) as described by standards such as ASTM F-2026. MEDTRONIC SOFAMOR DANEK expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. Do not use with implants from another manufacturer.

The purpose of this submission is to obtain clearance for the alternative material. All other aspects of the device including design, indications for use, and fundamental scientific technology are the same as the previous cleared BLOCK CEMENT RESTRICTOR-TITANIUM.

IV. **Intended Use:**

The CEMENT RESTRICTOR (CR) is intended for use as a cement restrictor in orthopedic surgeries in the femur and tibia in hip and knee replacement.

The CEMENT RESTRICTOR is NOT intended for any spinal indications.

V. **Substantial Equivalence:**

The CEMENT RESTRICTOR was demonstrated to be substantially equivalent to previously cleared devices such as BLOCK CR-TITANIUM (K013014) and Medtronic Sofamor Danek Cement Restrictor (K010528). A Design Review for the device was provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Richard W. Treharne
Sr. Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

DEC 0 5 2001

Re: K013663
Trade Name: Cement Restrictor (CR)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: JDK
Dated: November 5, 2001
Received: November 6, 2001

Dear Dr. Treharne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS. THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for

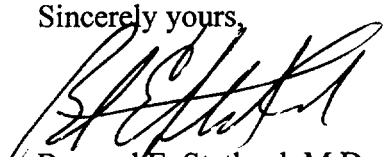
Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013663

Device Name: CEMENT RESTRICTOR (CR)

Indications for Use:

The CEMENT RESTRICTOR (CR) is intended for use as a cement restrictor in orthopedic surgeries in the femur and tibia in hip and knee replacement.

The CEMENT RESTRICTOR (CR) is NOT intended for any spinal indications.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use Yes **OR** **Over-the-counter Use** No
(Per 21 CFR 801.109)
(Optional 1-2-96)

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013663